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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,171

05/04/2006

Ulrike W. Klueh

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

06/27/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,171	Applicant(s) KLUEH ET AL.	
	Examiner Anne Marie S. Wehbe	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,9,14-16,19,20,25,27-29,32,35-39,50-54,57 and 59-62 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-4, 9, 14-16, 19-20, 25, 27-29, 32, 35-39, 50-54, 57, and 59-62 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Applicant's preliminary amendment received on 5/4/06 has been entered. Claims 5-8, 10-13, 17-18, 21-24, 26, 30-31, 33-34, 40-49, 55-56, 58, and 63-65 have been canceled. Claims 1-4, 9, 14-16, 19-20, 25, 27-29, 32, 35-39, 50-54, 57, and 59-62 are currently pending in the instant application.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-4, 9, 14-16, 19-20, 25, 27-28, 37-39, 51-52, 54, 59, drawn to an artificial tissue system or an artificial implant system comprising said artificial tissue system.

Group II, claims 29, 32, 35, 53, 57, drawn to methods for implanting a device in a biological system comprising placing a device in biological contact with a matrix, inserting cells into said matrix, and implanting said matrix into said biological system.

Group III, claim 36, drawn to a system for testing the effectiveness of an implant comprising an artificial tissue system.

Group IV, claim 50, drawn to a system for compatibilizing an implant with an implant-receiving biological system.

Group V, claim 60, drawn to an implant system comprising an implantable sensor and a matrix comprising a gel.

Group VI, claim 61, drawn to a method of improving the biocompatibility of a sensor with a tissue comprising placing a matrix comprising a gel between the sensor and the tissue.

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Group VII, claim 62, drawn to a method of implanting a device in a biological system comprising forming an implantation pocket in the biological system by injecting biocompatible material and implanting said device into said pocket.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the artificial tissue system as claimed does not constitute a special technical feature as the prior art as represented by US 2001/0000802 A1 (Soykan et al.) 3 May 2001 (of record, see IDS of 8/29/06) teaches both the artificial tissue system as claimed and the implant system as claimed. Specifically, Soykan et al. teaches implantable devices comprising a stent, medical electrical leads or electrodes, or catheters, and eukaryotic cells that produce at least one therapeutic agent, and said implantable systems further comprising a polymer composition (Soykan et al., page 11). Specific polymer compositions include fibrins, collagens, and alginates. Soykan further teaches that the polymer composition is a polymer matrix, see page 7, column 1. Soykan et al. also teaches methods of making the implantable device comprising either coating the device, such as a stent, with the polymer and then contacting the coated stent with the cells, or contacting the polymer with the cells and then coating the stent with the polymer/cell composition (Soykan et al., page 6). Thus, neither the artificial tissue system nor the implant system constitute a special technical feature.

Regarding inventions III and IV, the claimed “systems” appear to lack any specific elements, and it is further unclear based on the way the claim is written whether these are intended to be process claims or composition claims. They have been placed in separate groups in the interests of compact prosecution. However, amendment of the claims to clarify the invention may result in their being combined with one of the other groups identified above.

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It is further noted that 37 CFR 1.475 states that an international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

From the above, it is clear that multiple combinations are not allowed. Further, the allowed combinations do not include multiple products, multiple methods of using said product, and methods of making multiple products as claimed in the instant application, see MPEP § 1850 and 37 CFR 1.475. As set forth above, the claims clearly include multiple product and multiple methods of using said products.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not

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distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

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Dr. A.M.S. Wehbé

/Anne Marie S. Wehbé/
Primary Examiner, A.U. 1633